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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SMITH, PAUL B

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/749,499	Applicant(s) GUNDERSON, RICHARD C.	
	Examiner Paul B. Smith	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 12-13, 15, 23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller, Jr. ('220).

4. Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

5. It appears that Mueller, Jr. reasonably discloses every element of claims 1, 12-13, 15, 23 and 25.

6. Claims 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Nutting *et al.* ('489).

7. Nutting *et al.* discloses a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

8. It appears that Nutting *et al.* reasonably discloses every element of claims 16.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3763

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Nutting *et al.* ('489).

12. Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

13. Mueller, Jr. fails to disclose openings that are defined by circles, ovals, or a plurality of slots in different configurations.

14. Nutting *et al.* teaches a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

15. Nutting *et al.* fails to specifically disclose an oval opening.

16. The only difference between the prior art and the claims was a recitation of an oval shape of the claimed device and a device having the claimed oval shape would not

Art Unit: 3763

perform differently than the prior art device, the claimed device was not patentably distinct from the prior art

17. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Mueller, Jr. with the teachings of Nutting *et al.* to provide a marker band with a variety of opening configurations.

18. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of McBroom *et al.* ('108).

19. Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

20. Mueller, Jr. fails to disclose openings that are defined by slits in a proximal and distal region of the marker band.

21. McBroom *et al.* discloses a marker band comprising a top surface, a bottom surface and vertical perforations extended from the top surface to the bottom surface. (See Figure 6)

Art Unit: 3763

22. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Mueller, Jr. with the teachings of McBroom *et al.* to provide a marker band with a plurality of slits in the proximal and distal regions of the band.

23. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Eidenschink *et al.* ('734).

24. Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

25. Mueller, Jr. fails to disclose an outer surface defined by a fluorocarbon polymer.

26. Eidenschink *et al.* teaches a catheter defined by a fluorocarbon polymer such as polytetrafluoroethylene. (See Column 4 Lines 44-53)

27. It is well known in the art of catheter construction to use a fluorocarbon polymer as illustrated by Eidenschink *et al.* Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a fluorocarbon to manufacture the medical device of Mueller, Jr.

Art Unit: 3763

28. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Eidenschink *et al.* ('734) further in view of Hopkins ('489).

29. Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

30. Mueller, Jr. fails to disclose an outer surface defined by a fluorocarbon polymer.

31. Eidenschink *et al.* teaches a catheter defined by a fluorocarbon polymer such as polytetrafluoroethylene. (See Column 4 Lines 44-53)

32. It is well known in the art of catheter construction to use a fluorocarbon polymer as illustrated by Eidenschink *et al.* Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a fluorocarbon to manufacture the medical device of Mueller, Jr.

33. Eidenschink *et al.* fails to disclose a core member that is a guidewire.

34. Hopkins teaches placing a marker band on a guidewire. (See Column 1 Lines 17-20)

Art Unit: 3763

35. Thus, it would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Mueller, Jr. with the teachings of Hopkins such that the marker band is disposed on a guidewire.

36. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nutting *et al.* ('489) in view of McBroom *et al.* ('108).

37. Nutting *et al.* discloses a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

38. Nutting *et al.* fails to disclose one or more slits in the proximal or distal end regions of the marker band.

39. McBroom *et al.* teaches a marker band comprising slits in the proximal and distal end regions of the marker band. (See Figure 6 and 7)

40. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Nutting *et al.* with the teachings of McBroom *et al.* to provide a marker band with one or more slits in the proximal and distal end regions.

Art Unit: 3763

41. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenthal *et al.* ('903) in view of Nutting *et al.* ('489).

42. Rosenthal *et al.* discloses a marker band with a generally cylindrical body and longitudinal deflections defined in the proximal and distal end. (See Figure 9a-b)

43. Rosenthal *et al.* fails to disclose a marker band with one or more slots defined in the body section.

44. Nutting *et al.* teaches a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

45. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Rosenthal *et al.* with the teachings of Nutting *et al.* to provide a marker band with longitudinal deflections and one or more slots.

46. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford *et al.* ('822) in view of Nutting *et al.* ('489).

47. Crawford *et al.* discloses a method of securing a marker band to a balloon catheter comprising the steps of: providing a catheter, disposing a marker band over the catheter, and spray coating the marker band. (See Column 9 Lines 9-12)

48. Crawford *et al.* fails to disclose a marker band comprising slots.

49. Nutting *et al.* teaches a marker band with a circular hole and with two slots. In one configuration the slots are aligned on either side of the marker band. In another configuration the slots are offset on either side of the marker band. (See Figure 8-10)

50. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Crawford with the teachings of Nutting *et al.* to provide a method of securing a marker band with openings to a medical device.

51. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. ('220) in view of Nebergall *et al.* ('095).

52. Mueller, Jr. discloses a medical device comprising a tubular member (16); a radiopaque marker band (10) with an inner surface (not referenced), an outer surface (not referenced) and an opening (12); and an outer layer (19). (See Figure 2)

53. Mueller, Jr. fails to disclose an outer layer comprising multiple segments.

54. Nebergal *et al.* teaches a band disposed over an inner tubular member and an outer layer with multiple segments extending over the band. (See Figure 4)

Response to Arguments

55. Applicant's arguments, see page 9, filed 7/5/2006, with respect to the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.

56. Applicant's arguments, see page 9, filed 7/5/2006, with respect to claims 20 and 24 have been fully considered and are persuasive. The rejection of claims 20 and 24 has been withdrawn.

57. Applicant's arguments, see page 10, filed 7/5/2006, with respect to the rejection(s) of claim(s) 1 under 35 U.S.C. 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Mueller, Jr. ('220).

58. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


59. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

60. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

61. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith
Examiner
Art Unit 3763

PBS
August 23, 2006


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